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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,908	07/21/2003	Paul John Kawula	50623.245	5357

7590 09/27/2006  
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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/623,908	KAWULA, PAUL JOHN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-46 is/are pending in the application.
- 4a) Of the above claim(s) 9-21, 24-26 and 30-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-8, 22, 23 and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Claims 9-21,24-26,30-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/27/06.

### *Claim Rejections - 35 USC § 102*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-7,22,27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Brandau et al. (6709379). Fig. 5a shows a metal substrate layer **2**, an oxide layer **6** *between* the metal substrate and an outer ceramic layer **14**. Brandau discloses the implant can be a metal stent, col. 7, line 18. Brandau additionally discloses different oxide layers to cover the stent, col. 8, lines 18-23. Brandau also discloses a drug **5** (col. 7, line 31) can be used with a ceramic layer, col. 8, lines 25-28. Brandau also discloses the implant can have an oxide layer and a ceramic layer, col. 3, lines 26-28. It can be construed that the oxide layer is a less porous region at the attachment to the surface of the metal implant body because the surface **7** where connection occurs has no openings for drugs to be released and the outer region where the ceramic and oxide layer is connect **8** is more porous because of the openings.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brandau et al. '379 in view of Alt (6099561). Brandau is explained above. However, Brandau fails to disclose an alternative drug for use in the cavities of the implantable device or specific types of metals used for stents. Alt discloses that drugs can be incorporated with ceramic coated stent implants, col. 10, lines 42-61. Alt additionally teaches various metals, such as steel for making stents, col. 7, lines 44-49. It would have been an obvious expedient to one of ordinary skill in the art to utilize steel for the stent as taught by Alt for the stent of Brandau et al. because of its abundance and radiopacity. Additionally, it would have been obvious to one of ordinary skill in the art to incorporate other types of drugs, such as anti-inflammatories as taught by Alt in the stent of Brandau such that it helps in preventing restenosis or inflammation of the vessel.

***Response to Arguments***

Applicant's arguments filed 3/14/06 have been fully considered but they are not persuasive. Applicant argues that Brandau does not disclose the ceramic component connected at a second less porous region. The examiner is interpreting the claimed

elements "porous regions" in this way: the outer connection surface between the ceramic and the oxide is the more porous region because it has the drug cavities. The attachment region where the oxide connects with the implant surface is a less porous region since no cavities exist for drugs. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054, 1055. Thus, Brandau can be said to connect the ceramic through this second less porous region.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

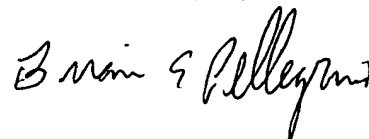
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (7:30am-5pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive, flowing style.